

**REMARKS**

Claims 1-10, 12-16 and 18-40 are pending in the present application. Claims 32-39 have been withdrawn from consideration. By virtue of this response, claims 1-5, 16, 20-24, and 40 have been amended. Claims 6-10, 12-15, 18-19, and 25-31 have been reiterated. Claims 1-10, 12-16, 18-31, and 40 are currently under consideration.

Amendment and cancellation of certain claims is in no way an admission of or acquiescence to the Examiner's rejection and is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Applicants expressly reserve the right to pursue identical or similar claims in other patent applications that are identical or similar to the claims amended or canceled in this response.

**Amendments to the Specification**

The Specification has been amended to update the status of the pending case as a CIP of now issued U.S. Patent No. 6,524,577.

**Restriction/Election**

Applicants acknowledge the finality of the restriction requirement.

**Claim Objections**

The Examiner has objected to claims 16 and 31.

**Claim 16**

The Examiner has objected to claim 16 under 37 CFR 1.75(c) as being in improper form because a multiply dependent claim should depend from another in the alternative form only. The

Examiner suggests that claim 16 “should have a ‘one’ inserted between “any” and “of” at line 1, claim 16.

Applicants have amended claim 16 to insert the term ‘one’ between “any” and “of,” as suggested by the Examiner. Accordingly, this ground for objection is now moot. Applicants respectfully request that it be withdrawn.

#### Claim 31

The Examiner has objected to claim 31. The Examiner suggest that claim 31 should have the term “one” inserted at line 2 after “than” and before “metabolite,” in order to be consistent with other claims.

Applicants have inserted the term “one” as suggested by the Examiner. This corrects a typographical error in the claim. Accordingly, Applicants respectfully request that this ground for objection be withdrawn.

#### **Rejections under 35 USC §112, first paragraph**

Claims 1-31 and 40 are rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the enablement requirement.

#### The Examiner’s Rejection

The Examiner alleges that the claims 1-31 and 40 contain subject matter that was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner requires a deposit of the microorganism to satisfy the requirements of 35 USC §112, first paragraph.

Applicant's Response

Applicants have deposited the material in compliance with the Budapest Treaty. A receipt of the deposit form, along with a statement by the attorney of record and Registration No. that the specific strain will be irrevocably and without restriction or condition be released to the public upon the issuance of this patent application is included with this response.

This ground for rejection is therefore moot. Applicants respectfully request that it be withdrawn.

**Rejections under 35 USC §112, second paragraph**

The Examiner has rejected claims 1-31 and 40 under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claims 1-31 and 40: Biologically Pure

The Examiner has rejected claims 1-31 and 40 as vague and indefinite for failing to clearly recite that the strain has been biologically purified. The Examiner suggest that the phrase "biologically pure" should be inserted before "Streptomyces sp. strain" at line 1 of claim 1 and at the first occurrence at line 1 of claim 40, respectively.

Claims 1 and 40 have been amended as suggested by the Examiner. Accordingly, this ground for rejection is now moot. Applicants respectfully request that it be withdrawn.

Claim 2

The Examiner has rejected claim 2 as being vague and indefinite for the recitation of "about 925 and about 865." The Examiner asserts that the lower range should come before the upper range.

For purposes of clarity, Applicants have amended claims 2, 4, 21, and 23 to read “about 865 and about 925.” The amendment does not in any way alter the scope of the claim.

This ground for rejection is now moot. Applicants respectfully request that it be withdrawn.

Claims 2-10, 12-16, and 18-31

The Examiner has rejected claims 2-10, 12-16, and 18-31 as indefinite, arguing that it is unclear what units of molecular weight are intended in the claims.

The claims have been amended to clarify that the molecular weights are in Daltons. This ground for rejection is now moot. Applicants respectfully request that it be withdrawn.

Claim 4

The Examiner argues that claim 4 is redundant, and suggests that it change dependency from claim 2.

Applicants respectfully traverse this ground for rejection. Claim 4 is not redundant, because neither claim 1 nor claim 2 is directed to a metabolite wherein the metabolite is heat and base stable and acid labile. Claim 4 is therefore not redundant.

Claims 2-10, 12-16, and 18-31

The Examiner alleges that claims 2-10, 12-16, and 18-31 are rendered vague and indefinite when alternatively dependent upon claim 40 since the term “metabolite” lacks antecedent basis.

Claim 40 has been amended to refer to the metabolite of claim 1. Claims 2-10, 12-16, and 18-31 therefore have the correct antecedent basis. This ground for rejection is now moot.

Claim 5

The Examiner has rejected claim 5 as indefinite. Specifically, the Examiner alleges that claim 5 is redundant and should be cancelled.

Applicants respectfully disagree. Claim 4 is to a metabolite of claim 1 or claim 40. The metabolite is heat and base stable, is acid labile and has a molecular weight  $[M+H^+]$  between about 865 Daltons and about 925 Daltons. Claim 5 is to the metabolite of claim 4, wherein wherein the molecular weight is selected from the group consisting of about 866.5 Daltons, about 882.5 Daltons, about 898.4 Daltons, about 892.5 Daltons, about 908.5 Daltons and about 924.5 Daltons.” Claim 5 is therefore not redundant. Applicants respectfully request that this ground for rejection be withdrawn.

**Double Patenting**A. Double Patenting under 35 U.S.C. § 101

The Examiner has rejected claims 12-14, 16, 18-19, and 40 as double patenting under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 3-5, and 11-12 of prior U.S. Patent No. 6,524,577. The Examiner alleges that claims 12-14, 16, 18-19, and 40 are no different than the patented claims 1, 3-5, and 11-12 of U.S. Patent No. 6,524,577. The Examiner argues that the claims are directed to the patented strain of U.S. Patent No. 6,524,577.

Statutory type double patenting prevents two patents from issuing on the same invention. “The same invention means identical subject matter.” MPEP § 804 II. A. According the MPEP § 804 II. A., “a reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent.” If there is an embodiment of the invention that falls within the scope of one claim, but not the other, “then identical subject matter is not defined by both claims and statutory double patenting does not exist.”

Claim 40 has been amended refer to a metabolite. Dependent claims 12-14, 16, 18-19 are also to a metabolite strain. The cited claims of U.S. Patent No. 6,524,577 are to a *Streptomyces sp.* strain. There is no identical subject matter between the present application and U.S. Patent No. 6,524,577, as required by 35 U.S.C. § 101. Since identical subject matter is not defined by the claims of the pending patent application and issued U.S. Patent No. 6,524,577, the statutory double patenting is improper. Applicants respectfully request that this ground for rejection be withdrawn.

#### B. Obviousness-Type Double Patenting

The Examiner has rejected claims 1-10, 12-16, 18-31, and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,524,577.

Along with this response, Applicants have terminally disclaimed any additional patent term over U.S. Patent No. 6,524,577. This ground for rejection is now moot. Applicants respectfully request that it be withdrawn.

#### **Rejections under 35 USC § 102(b)/103**

Claims 1-10, 12-16, 18-31, and 40 are rejected under 35 USC §102(b) as allegedly being anticipated by or, in the alternative, under USC 103(a) as obvious over Breinholt *et al.*

#### The Examiner's Rejection

The Examiner alleges that the claims are identical to the disclosure of Breinholt *et al.* The Examiner further asserts, without providing any support, that any difference between the claims and the disclosure is so slight that as to render the claims obvious.

Breinholt *et al.* fail to anticipate, or render obvious, the pending claims.

### Summary of the Claimed Invention

The presently claimed invention is to a metabolite produced by a biologically pure *Streptomyces sp.* strain selected from a *Streptomyces sp.* strain having all the identifying characteristics of the strain deposited with NRRL with Accession No. B-30145; and mutants of the strain with NRRL Accession No. B-30145, wherein the mutants have all the identifying characteristics of NRRL No. B-30145; and wherein the metabolite is in a non-naturally occurring environment and exhibits activity against plant pathogenic fungi.

### Summary of the Breinholt *et al.* Reference

The Breinholt *et al.* reference discloses metabolites produced by the genus *Penicillium*. The only reference in Breinholt *et al.* to *Streptomyces sp.* is to macrolides that are not the subject of the Breinholt *et al.* reference. The reference does not disclose any *Streptomyces* strain having the identifying characteristics of the strain deposited with NRRL Accession No. B-30145, and mutants thereof.

### Breinholt *et al.* Do Not Anticipate the Presently Claimed Invention

In order to anticipate under § 102(b), every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Because Breinholt *et al.* fail to show every element of the claimed invention, Breinholt *et al.* fail to anticipate the presently claimed invention.

The Breinholt *et al.* reference does not disclose a metabolite from a *Streptomyces* strain that has all the identifying characteristics of the *specific* strain in the pending claims. In particular, Breinholt *et al.* fail to disclose a *Streptomyces sp.* strain having all the identifying characteristics of the strain deposited with NRRL with Accession No. B-30145 (or mutants thereof). Instead, Breinholt *et al.* disclose metabolites produced by *Penicillium sp.* The Abstract discloses specific compounds from the fungus *Penicillium*. Further, the Summary of the invention at column 2, lines 4-5, teaches that the compounds disclosed in the Abstract are “produced by the fungal genus

*Penicillium*.” At column 3, lines 7-9, Breinholt *et al.* disclose that “compounds of formula I and II are obtainable as naturally or chemically modified metabolites from microorganisms such as fungi, especially from a fungus of the genus Penicillium.” Nowhere does Breinholt *et al.* disclose or suggest that the metabolites of the *Penicillium* strain described in the Breinholt *et al.* reference are equivalent to a metabolite produced by the presently claimed *Streptomyces sp.* strain.

Because Breinholt *et al.* fail to disclose a metabolite from the specifically claimed strain, Breinholt *et al.* fail to anticipate the presently claimed invention.

### **Breinholt *et al.* Do Not Render the Presently Claimed Invention Obvious**

The Examiner argues that “if there is some unidentified claim characteristic for which to provide some difference between the ...claims and cited reference ... then such difference is considered to be so slight as to render the claims obvious therefore.” The Examiner concludes that it would have been obvious for one of skill in the art to select for a metabolite from the *Streptomyces* strain or mutant having all the identifying characteristics of the strain deposited with NRRL with Accession No. B-30145 based solely on the disclosure of Breinholt *et al.*

### **Breinholt *et al.* Distinguished**

35 U.S.C. § 103(a) requires that “differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a). The prima facie case must satisfy three requirements: 1) the references must teach or suggest all the claim limitations; 2) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 3) the modification or combination must have a reasonable chance of success.

First, as previously discussed, the Breinholt *et al.* reference fails to meet every limitation of the present claims. The currently claimed invention is to metabolite produced by a *specific*



biologically pure *Streptomyces sp.* strain (and mutants have all the identifying characteristics of the strain), wherein the metabolite is in a non-naturally occurring environment and exhibits activity against plant pathogenic fungi. Breinholt *et al.* do not disclose or suggest that the metabolites of the *Penicillium* strain described by Breinholt *et al.* are equivalent to a metabolite produced by the claimed *Streptomyces sp.* strain. Breinholt *et al.* therefore fail to meet every limitation of the claim.

Second, there is no motivation to obtain the metabolite produced by any *Streptomyces sp.* strain based on the disclosure of Breinholt *et al.* Breinholt lacks any suggestion of a metabolite from the *specific* strain of *Streptomyces sp.* of the presently claimed invention. Absent such motivation or suggestion to modify the teachings of Breinholt *et al.*, the presently claimed invention is not obvious over the Breinholt *et al.* reference.

Third, Breinholt *et al.* provide no reasonable expectation of success for one of skill in the art to modify the reference and make a metabolite produce by the specific strain of *Streptomyces sp.* The reference provides no reason to conclude that one of skill in the art could make the presently claimed metabolite from a streptomyces strain having all the identifying characteristics of the strain deposited with NRRL with Accession No. B-30145, based on the disclosure of *Penicillium* metabolites disclosed by Breinholt *et al.*

Applicants respectfully request that this ground for rejection be withdrawn.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 311412001820. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

**Dated January 28, 2004**

Respectfully submitted,

By 

Timothy A. Worrall

Registration No.: 54,552

MORRISON & FOERSTER LLP

755 Page Mill Road

Palo Alto, California 94304

(415) 268-7000